

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP,
ASTRAZENECA UK LIMITED,
IPR PHARMACEUTICALS, INC.,
SHIONOGI SEIYAKU KABUSHIKI KAISHA,

Plaintiffs,

v.

SANDOZ INC.,

Defendant.

Civil Action No.: 07-807-JJF-LPS

**PLAINTIFFS' REPLY TO AFFIRMATIVE DEFENSES AND
COUNTERCLAIMS OF DEFENDANT SANDOZ INC.**

Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals, Inc., and Shionogi Seiyaku Kabushiki Kaisha (collectively, "Plaintiffs"), through their undersigned counsel, reply to the affirmative defenses and counterclaims of Defendant Sandoz Inc. as follows.

REPLY TO AFFIRMATIVE DEFENSES

First Affirmative Defense - Invalidity of the '314 Patent

29. One or more claims of the '314 patent are invalid for failure to comply with one or more of the requirements of 35 U.S.C. §§ 101 *et seq.*

Answer: Plaintiffs deny the allegations in Paragraph 29.

Second Affirmative Defense -Unenforceability of the '314 Patent

30. On information and belief, the '314 patent is unenforceable due to the inequitable conduct of one or more persons who owed a duty of candor to the United States Patent and Trademark Office ("PTO") with respect to the '314 patent and/or U.S. Patent No. 5,260,440 ("the '440 patent") who, with the intent to deceive the PTO, violated their duty of candor to the PTO by intentionally failing to disclose material information to the PTO and by submitting a declaration in support of patentability that contained false and misleading information.

Answer: Plaintiffs deny the allegations in Paragraph 30.

31. The U.S. patent application which issued as the '440 patent was filed with the PTO by Wenderoth, Lind & Ponack on June 12, 1992, and claims priority to Japanese Application Serial No. 188015, filed July 1, 1991.

Answer: Plaintiffs admit that an application that matured into the '440 patent was filed by an individual from the Wenderoth, Lind & Ponack firm on June 12, 1992 and claims priority to Japanese Application Serial No. 3-188015 filed on July 1, 1991. Plaintiffs deny the remaining allegations in Paragraph 31.

32. The U.S. patent application for the '440 patent lists Kentaro Hirai, Teruyuki Ishiba, Haruo Koike and Masamichi Watanabe as inventors.

Answer: Plaintiffs admit the allegations in Paragraph 32.

33. The '440 patent was issued by the PTO on November 9, 1993.

Answer: Plaintiffs admit the allegations in Paragraph 33.

34. European patent application serial number 92111090.4 ("Corresponding European Patent Application") is the European counterpart to the U.S. application for the '440 patent.

Answer: Plaintiffs admit the allegations in Paragraph 34.

35. The Corresponding European Patent Application was filed with the European Patent Office by Vossius & Partner on June 30, 1992, and claims priority to Japanese Application Serial No. 188015.

Answer: Plaintiffs admit that the Corresponding European Patent Application was filed with the European Patent Office by an individual from the Vossius & Partner firm on June 30, 1992 and claims priority to Japanese Application Serial No. 3-188015. Plaintiffs deny the remaining allegations in Paragraph 35.

36. The Corresponding European Patent Application lists as inventors Kentaro Hirai, Teruyuki Ishiba, Haruo Koike and Masamichi Watanabe.

Answer: Plaintiffs admit the allegations in Paragraph 36.

37. As filed, claim 1 of the Corresponding European Patent Application was identical to original claim 1 of the U.S. Patent application for the '440 patent.

Answer: Plaintiffs admit that the text of original claim 1 filed in the Corresponding European Patent Application to be interpreted under European patent law was identical to the text of original claim 1 of the U.S. Patent Application to be interpreted under U.S. law. Plaintiffs deny the remaining allegations in Paragraph 37.

38. On October 7, 1992, the European Patent Office transmitted a European search report ("European Search Report") concerning application number 92111090.4 to Vossius & Partner, the patent attorneys and/or agents responsible for prosecuting the Corresponding European Patent Application in the European Patent Office.

Answer: Plaintiffs admit that in October 1992, the European Patent Office transmitted a European Search Report in connection with the Corresponding European Patent Application to the Vossius & Partner firm. Plaintiffs deny the remaining allegations in Paragraph 38.

39. Under "DOCUMENTS CONSIDERED TO BE RELEVANT", the European Search Report listed one document, "EP-A-O 367 895 (SANDOZ)".

Answer: Plaintiffs admit that the European Search Report listed "EP-A-0 367 895 (SANDOZ)" under "Documents Considered to be Relevant." Plaintiffs deny the remaining allegations in Paragraph 39.

40. The European Search Report stated that EP-A-O 367 895 (SANDOZ) was a category "X" reference which, according to the European Search Report, is "particularly relevant if taken alone."

Answer: Plaintiffs admit that in the European Search Report, EP-A-0 367 895 (SANDOZ) was categorized in accordance with European patent practice on a form which contained pre-printed text reading "X : particularly relevant if taken alone." Plaintiffs deny the remaining allegations in Paragraph 40.

41. On information and belief, the named inventors and/or one or more other persons owing a duty of candor to the PTO were aware that the reference EP-A-O 367 895

(SANDOZ) was cited in the European Search Report as a Category "X" reference.

Answer: Plaintiffs deny the allegations in Paragraph 41.

42. On August 27, 1998, Kentaro Hirai, Teruyuki Ishiba, Haruo Koike and Masamichi Watanabe filed an application to reissue the '440 patent ("Reissue Application").

Answer: Plaintiffs admit that the Reissue Application was filed on August 27, 1998 and identifies Kentaro Hirai, Teruyuki Ishiba, Haruo Koike, and Masamichi Watanabe as inventors. Plaintiffs deny the remaining allegations in Paragraph 42.

43. In a declaration filed in support of the Reissue Application ("Declaration"), it is stated that: "Patentee claimed more than he had a right to claim by reason of the disclosure of European Patent Application 0 367 895, published May 16, 1990. The amended claims of the reissue application are considered to fully overcome any grounds for unpatentability based upon this reference."

Answer: Plaintiffs admit the allegations in Paragraph 43.

44. In the Reissue Application, Kentaro Hirai, Teruyuki Ishiba, Haruo Koike and Masamichi Watanabe acknowledged that EP-A-O 367 895 (SANDOZ) was material to the application that issued as the '440 patent.

Answer: Plaintiffs deny the allegations in Paragraph 44.

45. EP-A-O 367 895 (SANDOZ) was material to the application that issued as the '440 patent.

Answer: Paragraph 45 contains legal conclusions to which no response is required.

To the extent that a response is required, Plaintiffs deny the allegations in Paragraph 45.

46. The Reissue Application issued as the '314 patent on August 7, 2001.

Answer: Plaintiffs admit the allegations in Paragraph 46.

47. The named inventors and/or one or more other persons owing a duty of candor to the PTO failed to advise the PTO Patent Examiner responsible for prosecuting the '440 patent that EP-A-O 367 895 (SANDOZ) was cited in the European Search Report issued in the Corresponding European Patent Application, and such failure to advise constituted a material misstatement and/or misrepresentation and/or omission.

Answer: Paragraph 47 contains legal conclusions to which no response is required.

To the extent that a response is required, Plaintiffs deny the allegations in Paragraph 47.

48. Upon information and belief, the failure to advise the PTO of EP-A-O 367 895 (SANDOZ) was carried out with the intent to deceive the PTO Patent Examiner so as to induce the PTO to issue the '440 patent.

Answer: Plaintiffs deny the allegation in Paragraph 48.

49. In the Declaration in the Reissue Application, it was stated that: "All errors corrected in this reissue application arose without any deceptive intention on the part of the applicant." The named inventors and/or one or more other persons owing a duty of candor to the PTO submitted the Declaration in support of patentability, and such submission constituted a material misstatement and/or misrepresentation and/or omission and, upon information and belief, was made with intent to deceive the Patent Examiner so as to induce the PTO to issue the '314 patent.

Answer: Paragraph 49 contains legal conclusions to which no response is required.

To the extent that a response is required, Plaintiffs admit that the Declaration in the Reissue Application stated that "All errors corrected in this reissue application arose without deceptive intention on the part of the applicant." Plaintiffs further admit that such Declaration was submitted by the Applicant of the Reissue Application to obtain a reissue of the '440 patent. Plaintiffs deny the remaining allegations in Paragraph 49.

Third Affirmative Defense - Non-Infringement of the '314 Patent

50. Sandoz's Rosuvastatin Calcium Tablets do not infringe any valid and enforceable claim of the '314 patent.

Answer: Plaintiffs deny the allegations in Paragraph 50.

Fourth Affirmative Defense - Failure to State a Claim

51. In Count II of the Complaint, Plaintiffs have failed to state a claim upon which relief can be granted.

Answer: Plaintiffs deny the allegations in Paragraph 51.

Fifth Affirmative Defense - Lack of Subject Matter Jurisdiction

52. The Court lacks subject matter jurisdiction over Count II of the Complaint.

Answer: Plaintiffs deny the allegations in Paragraph 52.

REPLY TO COUNTERCLAIMS

Sandoz's Allegations Pertaining to All of Sandoz's Counterclaims

53. The counterclaims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Patent Laws of the United States, 35 U.S.C. §§ 1 *et seq.*

Answer: Plaintiffs admit that Sandoz's counterclaims purport to arise under the Declaratory Judgment Act and the Patent Laws of the United States, but deny that they are valid or sustainable. With regard to the '460 patent, the '618 patent, and the '959 patent, Plaintiffs have moved to dismiss Defendants' counterclaims against these patents for lack of case or controversy. Any answer to allegations concerning the '460 patent, the '618 patent, or the '959 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4).

54. Subject matter jurisdiction of these counterclaims is proper under 28 U.S.C. §§ 1331 and 1338(a) and Rule 13, Fed. R. Civ. P.

Answer: Plaintiffs admit that this Court has subject matter jurisdiction over the counterclaims arising under 28 U.S.C. §§ 1331 and 1338(a) and Rule 13, Fed. R. Civ. P. with regard to the '314 patent. Plaintiffs deny the remaining allegations in Paragraph 54.

55. Venue as to Sandoz's counterclaims is proper under 28 U.S.C. §§ 1391(c) and 1400(b), and because Plaintiffs have commenced the underlying action in this District.

Answer: Plaintiffs admit that venue as to Sandoz's counterclaims is proper for the purposes of this action only. Plaintiffs deny the remaining allegations in Paragraph 55.

56. Counterclaim plaintiff Sandoz is a corporation operating and existing under the laws of the State of Colorado with its principal place of business at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540.

Answer: On information and belief, Plaintiffs admit that Sandoz is a corporation operating and existing under the laws of the state of Colorado with its principal place of business at 506 Carnegie Center Suite 400, Princeton, New Jersey 08540.

57. On information and belief, counterclaim defendant AstraZeneca Pharmaceuticals LP is a corporation operating and existing under the laws of Delaware with its principal place of

business at 1800 Concord Pike, Wilmington, Delaware 19803. Personal jurisdiction over AstraZeneca Pharmaceuticals LP is proper because AstraZeneca Pharmaceuticals LP is incorporated in Delaware and has purposely availed itself of the privilege of doing business in that State and has purposefully availed itself of this forum's benefits and privileges in this action. Further, AstraZeneca Pharmaceuticals LP maintains continuous and systematic contacts with the State of Delaware so as to reasonably allow jurisdiction to be exercised over it.

Answer: Paragraph 57 contains legal conclusions to which no response is required.

To the extent that a response is required, Plaintiffs admit that AstraZeneca Pharmaceuticals LP is a corporation operating and existing under the laws of Delaware with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803 and that personal jurisdiction over AstraZeneca Pharmaceuticals LP is proper for the purposes of this action only. Plaintiffs deny the remaining allegations in Paragraph 57.

58. On information and belief, counterclaim defendant AstraZenecaUK Limited is a corporation operating and existing under the laws of the United Kingdom with its principal place of business at 15 Stanhope Gate, London W1K 1LN, England. Personal jurisdiction over AstraZeneca UK Limited is proper because AstraZeneca UK Limited has purposely availed itself of the privilege of doing business in Delaware and has purposefully availed itself of this forum's benefits and privileges in this action. Further, AstraZeneca UK Limited maintains continuous and systematic contacts with the State of Delaware so as to reasonably allow jurisdiction to be exercised over it.

Answer: Paragraph 58 contains legal conclusions to which no response is required.

To the extent that a response is required, Plaintiffs admit that AstraZeneca UK Limited is a corporation operating and existing under the laws of the United Kingdom with its principal place of business at 15 Stanhope Gate, London W1K 1LN, England and admit that personal jurisdiction over AstraZeneca UK Limited is proper for purposes of this action only. Plaintiffs deny the remaining allegations in Paragraph 58.

59. On information and belief, counterclaim defendant IPR Pharmaceuticals, Inc. is a corporation operating and existing under the laws of Puerto Rico with its principal place of business at Carr 188 Lote 17, San Isidro Industrial Park, Canovanas, Puerto Rico 00729. Personal jurisdiction over IPR Pharmaceuticals, Inc. is proper because IPR Pharmaceuticals, Inc. has purposely availed itself of the privilege of doing business in Delaware and has purposefully availed itself of this forum's benefits and privileges in this action. Further, IPR Pharmaceuticals, Inc. maintains continuous and systematic contacts with the State of

Delaware so as to reasonably allow jurisdiction to be exercised over it.

Answer: Paragraph 59 contains legal conclusions to which no response is required.

To the extent that a response is required, Plaintiffs admit that IPR Pharmaceutical, Inc. is a corporation operating and existing under the laws of Puerto Rico with its principal place of business at Carr 188 Lote 17, San Isidro Industrial Park, Canovanas, Puerto Rico 00729 and admit that personal jurisdiction over IPR Pharmaceutical, Inc. is proper for purposes of this action only. Plaintiffs deny the remaining allegations in Paragraph 59.

60. On information and belief, counterclaim defendant Shionogi Seiyaku Kabushiki Kaisha is a corporation operating and existing under the laws of Japan with its principal place of business at 1-9, Doshomachi 3-chome, Chuo-ku, Osaka 541-0045 Japan. Personal jurisdiction over Shionogi Seiyaku Kabushiki Kaisha is proper because Shionogi Seiyaku Kabushiki Kaisha has purposely availed itself of the privilege of doing business in Delaware and has purposefully availed itself of this forum's benefits and privileges in this action. Further, Shionogi Seiyaku Kabushiki Kaisha maintains continuous and systematic contacts with the State of Delaware so as to reasonably allow jurisdiction to be exercised over it.

Answer: Paragraph 60 contains legal conclusions to which no response is required.

To the extent that a response is required, Plaintiffs admit that Shionogi Seiyaku Kabushiki Kaisha is a corporation operating and existing under the laws of Japan with its principal place of business at 1-9, Doshomachi 3-chome, Chuo-ku, Osaka 541-0045 Japan and admit that personal jurisdiction over Shionogi Seiyaku Kabushiki Kaisha is proper for purposes of this action only. Plaintiffs deny the remaining allegations in Paragraph 60.

61. The publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"), identifies drug products approved for sale by the Food and Drug Administration (the "FDA") under the Federal Food, Drug, and Cosmetic Act, and the Orange Book lists patents that protect approved drug products and their uses.

Answer: Plaintiffs admit that the publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"), identifies drug products approved for sale by the Food and Drug Administration (the "FDA") under Section 505 of the the Federal Food, Drug, and Cosmetic Act and lists, *inter alia*, patents that claim the active ingredient(s), drug products,

or a method of use involving an approved indication. Plaintiffs deny the remaining allegations in Paragraph 61.

62. The Orange Book lists the '314 patent, the '460 patent and the '618 patent with respect to rosuvastatin calcium tablets. On information and belief, the '959 patent was also listed in the Orange Book with respect to rosuvastatin calcium tablets, but was delisted sometime in 2007.

Answer: Plaintiffs admit that the Orange Book lists the '314 patent. With regard to the '460 patent, the '618 patent, and the '959 patent, Plaintiffs have moved to dismiss Defendants' counterclaims against these patents for lack of case or controversy. Any answer to allegations concerning the '460 patent, the '618 patent, or the '959 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4).

63. Pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 U.S.C. § 355(j)(2)(B), Sandoz certified to the FDA its belief that the '314 patent, the '460 patent, the '618 patent, and the '959 patent were invalid, unenforceable and/or would not be infringed by the manufacture, use or sale of Sandoz's Rosuvastatin Calcium Tablets, and Sandoz notified the Plaintiffs/counterclaim defendants of its belief that that the '314 patent, the '460 patent, and the '618 patent were invalid, unenforceable and/or would not be infringed by the manufacture, use or sale of Sandoz's Rosuvastatin Calcium Tablets.

Answer: Plaintiffs admit, on information and belief, that Sandoz has certified to the FDA regarding the '314 patent. With regard to the '460 patent, the '618 patent, and the '959 patent, Plaintiffs have moved to dismiss Defendants' counterclaims against these patents for lack of case or controversy. Any answer to allegations concerning the '460 patent, the '618 patent, or the '959 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4). Plaintiffs deny the remaining allegations in Paragraph 63.

64. Upon information and belief, one or more counterclaim defendants own and/or have the right to enforce the '314 patent, the '460 patent, the '618 patent and the '959 patent.

Answer: Plaintiffs admit the allegations in Paragraph 64 as to the '314 patent. With regard to the '460 patent, the '618 patent, and the '959 patent, Plaintiffs have moved to dismiss Defendants' counterclaims against these patents for lack of case or controversy. Any answer to

allegations concerning the '460 patent, the '618 patent, or the '959 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4).

ANSWER TO FIRST COUNTERCLAIM

65. The counterclaim defendants filed a Complaint against Sandoz in this district alleging that Sandoz has infringed the '314 patent.

Answer: Plaintiffs admit the allegations in Paragraph 65.

66. Sandoz incorporates by reference paragraphs 29-64 of this Answer as if fully set forth herein.

Answer: Plaintiffs reassert and incorporate by reference Plaintiffs' responses to paragraphs 29 through 64, as set forth above.

67. The '314 patent is invalid because it does not comply with one or more of the requirements of 35 U.S.C. §§ 101 *et seq.*

Answer: Plaintiffs deny the allegations in Paragraph 67.

ANSWER TO SECOND COUNTERCLAIM

68. Sandoz incorporates by reference paragraphs 29-67 of this Answer as if fully set forth herein.

Answer: Plaintiffs reassert and incorporate by reference Plaintiffs' replies to Paragraphs 29 through 67, as set forth above.

69. The '314 patent is unenforceable for inequitable conduct as alleged.

Answer: Plaintiffs deny the allegations in Paragraph 69.

ANSWER TO THIRD COUNTERCLAIM

70. Sandoz incorporates by reference paragraphs 29-69 of this Answer as if fully set forth herein.

Answer: Plaintiffs reassert and incorporate by reference Plaintiffs' responses to Paragraphs 29 through 69, as set forth above.

71. Sandoz's Rosuvastatin Calcium Tablets do not infringe any valid and enforceable claim of the '314 patent.

Answer: Plaintiffs deny the allegations in Paragraph 71.

ANSWER TO FOURTH COUNTERCLAIM - '460 PATENT

72. Sandoz incorporates by reference paragraphs 29-71 of this Answer as if fully set forth herein.

Answer: Plaintiffs have moved to dismiss Defendants' counterclaims against the '460 patent for lack of case or controversy. Any answer to allegations concerning the '460 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4). Plaintiffs reassert and incorporate by reference Plaintiffs' responses to Paragraphs 29 through 71, as set forth above.

73. One or more claims of the '460 patent are invalid for failure to comply with one or more of the requirements of 35 U.S.C. §§ 101 *et seq.*

Answer: Plaintiffs have moved to dismiss Defendants' counterclaims against the '460 patent for lack of case or controversy. Any answer to allegations concerning the '460 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4).

ANSWER TO FIFTH COUNTERCLAIM - '460 PATENT

74. Sandoz incorporates by reference paragraphs 29-73 of this Answer as if fully set forth herein.

Answer: Plaintiffs have moved to dismiss Defendants' counterclaims against the '460 patent for lack of case or controversy. Any answer to allegations concerning the '460 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4).

75. Sandoz's Rosuvastatin Calcium Tablets do not infringe any valid claim of the '460 patent.

Answer: Plaintiffs have moved to dismiss Defendants' counterclaims against the '460 patent for lack of case or controversy. Any answer to allegations concerning the '460 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4).

ANSWER TO SIXTH COUNTERCLAIM - '618 PATENT

76. Sandoz incorporates by reference paragraphs 29-75 of this Answer as if fully set forth herein.

Answer: Plaintiffs have moved to dismiss Defendants' counterclaims against the '618 patent for lack of case or controversy. Any answer to allegations concerning the '618 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4).

77. One or more claims of the '618 patent are invalid for failure to comply with one or more of the requirements of 35 U.S.C §§ 101 *et seq.*

Answer: Plaintiffs have moved to dismiss Defendants' counterclaims against the '618 patent for lack of case or controversy. Any answer to allegations concerning the '618 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4).

ANSWER TO SEVENTH COUNTERCLAIM - '618 PATENT

78. Sandoz incorporates by reference paragraphs 29-77 of this Answer as if fully set forth herein.

Answer: Plaintiffs have moved to dismiss Defendants' counterclaims against the '618 patent for lack of case or controversy. Any answer to allegations concerning the '618 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4).

79. Sandoz's Rosuvastatin Calcium Tablets do not infringe any valid claim of the '618 patent.

Answer: Plaintiffs have moved to dismiss Defendants' counterclaims against the '618 patent for lack of case or controversy. Any answer to allegations concerning the '618 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4).

ANSWER TO EIGHTH COUNTERCLAIM - '959 PATENT

80. Sandoz incorporates by reference paragraphs 29-79 of this Answer as if fully set forth herein.

Answer: Plaintiffs have moved to dismiss Defendants' counterclaims against the '959 patent for lack of case or controversy. Any answer to allegations concerning the '959 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4).

81. One or more claims of the '959 patent are invalid for failure to comply with one or more of the requirements of 35 U.S.C. §§ 101 *et seq.*

Answer: Plaintiffs have moved to dismiss Defendants' counterclaims against the '959 patent for lack of case or controversy. Any answer to allegations concerning the '959 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4).

ANSWER TO NINTH COUNTERCLAIM - '959 PATENT

82. Sandoz incorporates by reference paragraphs 29-81 of this Answer as if fully set forth herein.

Answer: Plaintiffs have moved to dismiss Defendants' counterclaims against the '959 patent for lack of case or controversy. Any answer to allegations concerning the '959 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4).

83. Sandoz's Rosuvastatin Calcium Tablets do not infringe any valid claim of the '959 patent.

Answer: Plaintiffs have moved to dismiss Defendants' counterclaims against the '959 patent for lack of case or controversy. Any answer to allegations concerning the '959 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4).

* * *

Plaintiffs deny all remaining allegations not specifically stated herein and deny that Sandoz is entitled to any of the relief requested or any relief at all.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request this Court to enter judgment against Sandoz as follows:

- (a) dismissing Sandoz's Counterclaims with prejudice;
- (b) finding that this is an exceptional case and granting AstraZeneca's reasonable attorney fees pursuant to 35 U.S.C. § 285; and
- (b) awarding Plaintiffs any further and additional relief as this Court deems just and proper.

<p>Ford F. Farabow Charlie E. Lipsey York M. Faulkner FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P. 901 New York Avenue, N.W. Washington, D.C. 20001 Telephone: (202) 408-4000 Facsimile: (202) 408-4400</p> <p>Henry J. Renk FITPATRICK, CELLA, HARPER & SCINTO 30 Rockefeller Plaza New York, NY 10112 Telephone: (212) 218-2100 Facsimile: (212) 218-2200</p> <p><i>Of Counsel for Plaintiffs,</i> AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals, Inc., and Shionogi Seiyaku Kabushiki Kaisha</p> <p>Dated: March 21, 2008</p>	<p>Respectfully Submitted:</p> <p><u>/s/ Mary W. Bourke</u> Mary W. Bourke (#2356) CONNOLLY BOVE LODGE & HUTZ LLP 1007 N. Orange Street Wilmington, DE 19899 Telephone: (302) 658-9141 Facsimile: (302) 658-5614 mbourke@cblh.com <i>Attorneys for Plaintiffs</i></p>
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CERTIFICATE OF SERVICE

I hereby certify on this 21st day of March, 2008 I electronically filed the foregoing PLAINTIFFS' REPLY TO AFFIRMATIVE DEFENSES AND COUNTERCLAIMS OF DEFENDANT SANDOZ INC. with the Clerk of Court using CM/ECF which will send notification of such filing to the following:

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The undersigned counsel further certifies that, on March 21, 2008, copies of the foregoing document were also served upon the following individuals in the manner indicated:

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